



DEPARTMENT OF THE ARMY

HEADQUARTERS, U. S. ARMY DENTAL ACTIVITY
FORT HUACHUCA, ARIZONA 85613-7040

REPLY TO
ATTENTION OF
DSBJ-CDR (100)

11 May 1999

MEMORANDUM FOR ALL DENTAC PERSONNEL

SUBJECT: U.S. Army Dental Activity (DENTAC) Policy Letter
#99-14 -- Policy on Submission of Medical Material Complaints

1. The purpose of this memorandum is to establish policy for lodging complaints involving a standard or non-standard medical item found to be injurious or unsatisfactory.

2. Anyone who wishes to make a complaint involving a standard or non-standard medical item found to be injurious or unsatisfactory must initiate a SF 380-101 (Reporting and Processing Medical Materiel Complaints/Quality Improvement Report). An example and instructions for completion of this form are attached. The Team NCO/Clinic NCOIC will provide the forms and assistance for preparation of the form. The three types of complaints are as follows:

a. Type I: These complaints are for materiel which by use or test is determined to be harmful or defective to the extent that its use has caused or may cause death. Immediate action must be taken to report such items and to suspend their use. Once the Materiel Branch receives a Type I report, issue of the item will also be suspended. NOTE: Only medical and dental officers familiar with details of the complaint can initially classify it as a TYPE I and they must be the individual to sign.

b. TYPE II: These complaints are utilized to report materiel, other than equipment, suspected of being harmful, defective, deteriorated or unsuitable for use. This type of complaint must be reported immediately. Upon identification, it will be suspended from use and issue.

c. TYPE III: These types of complaints are reserved to report equipment which is determined to be unsatisfactory because of malfunction, designs, defects (attributable to faulty material, workmanship, or quality inspection) or performance. A TYPE III complaint does not necessarily require suspension of the item.

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3. The complaint form must be completed, signed, and given to the Team NCO/Clinic NCOIC, who will forward it to the NCOIC, Materiel Branch (Health Center). There it will be assigned a voucher number and signed by the accountable officer. Complaints on medical equipment will be staffed through Medical Maintenance Branch to the Chief of Logistics who will determine if it is to be resolved locally, or forwarded to DSCP for further processing. If it is resolved locally, a memorandum will be attached to the form and returned to the originator, with file copies retained in the Materiel Branch.

4. If Chief, Logistics Division determines that the complaint is to be forwarded, it will be returned to Materiel Branch where the NCOIC will forward it to the proper activity for evaluation.

5. The activity responsible for the evaluation will investigate the complaint and return their results and proposed resolution to the Materiel Branch.

6. Items put on suspension as a result of a materiel complaint will be marked as such and maintained until resolution. Once a reply is received, the suspended materiel will be processed in accordance with DSCP instructions.

7. Questions on the above procedure should be addressed to the Team NCO/NCOIC, or the NCOIC, Materiel Branch (Health Center).

//Original Signed By//

HARLAND G. LEWIS, JR.
Colonel, Dental Corps
Commanding

DISTRIBUTION:

MEDDAC Risk Manager
DENTAC Risk Manager (L. Cook)
Medical Maintenance Branch (MXCJ-LO-CE)
DENTAC Supply

APPENDIX A

MEDICAL MATERIEL COMPLAINTS

Standard Form 380-101 will be completed as follows:

1. Date - Date complaint form is filled.
2. No. - Enter the Materiel Branch voucher number form, the W61DEW voucher register.
3. Block 1a and 1b - leave blank.
4. Block 2 - National Stock Number (NSN), MIIN or part number of the subject of the complaint.
5. Block 3 - Nomenclature of the subject of the complaint.
6. Blocks 4 through 6 - Name and address of manufacturer and vendor, and contract number under which the item was purchased.
7. Block 7a - leave blank.
8. Block 7b - Document number under which item was requisitioned.
9. Blocks 8 through 17 - Applicable information on subject of the complaint, to include in block 17 the number of items in suspension.
10. Block 18 - For Type I complaints ONLY. This information is to be provided by the attending physician/dentist.
11. Block 19 - Detailed reason for the complaint, to include description of failure, actions taken, if any, to correct the problem. If the item is in service, length of service, or date put in service.
12. Block 20 - Name and phone number of individual submitting the complaint.
13. Block 21 - Name, date, and phone number of Medical Supply Officer.
14. Block 22 - Actions recommended by the initiator to correct the problem.
15. Block 23 - Actions taken, such as what was done to make item serviceable, if item was taken out of service, or an advisory issued to users, etc.

REPORTING AND PROCESSING MEDICAL MATERIEL COMPLAINTS/ QUALITY IMPROVEMENT REPORT		DATE	
		NO.	
TO		FROM	
TYPE OF COMPLAINT ▶ <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III		18. FOR VA USE <input type="checkbox"/> QUALITY COMPLAINT <input type="checkbox"/> NEW ITEM <input type="checkbox"/> SIMILAR ITEM	
2. NATIONAL STOCK NO.		3. ITEM DESCRIPTION	
4. NAME AND ADDRESS OF MANUFACTURER		5. NAME OF CONTRACTOR (If other than the manufacturer)	
		6. CONTRACT NO. OR PURCHASE ORDER NO.	
7A. VA DEPOT VOUCHER NO.	7B. DOD REQUISITION NO.	8. LOT NO.	
9. CONTROL NO.	10. MANUFACTURER'S SERIAL NO.	11. MODEL NO.	
12. DATE MANUFACTURED	13. DATE PACKED	14. EXPIRATION DATE	
15. SOURCE (Name of Depot)	16. QUANTITY ON HAND	17. QUANTITY SUSPENDED	
COMPLETE ITEM 18A. THROUGH 18F. FOR DOD TYPE I COMPLAINTS ONLY			
18A. TOTAL NO. PATIENTS INVOLVED		18B. TOTAL NO. REACTIONS	
		18C. SEVERE OR UNUSUAL REACTIONS	
18D. REACTIONS REQUIRING HOSPITALIZATION	18E. LENGTH OF HOSPITALIZATION	18F. VACCINE	
		<input type="checkbox"/> INITIAL <input type="checkbox"/> BOOSTER INTERVAL _____	
19. CAUSE OF COMPLAINT (Explanation of unsatisfactory condition, deficiency, or description of reaction. Complete 19 through 22 for ALL complaints.)			
20A. TYPED NAME OF INITIATOR (For Type I MC/DC/NC)		20B. AUTOVON/FTS TELEPHONE NO.	
		20C. COMMERCIAL TELEPHONE NO.	
21A. TYPED NAME OF SUPPLY OFFICER		21B. SIGNATURE OF SUPPLY OFFICER	
		21C. DATE	
21D. AUTOVON/FTS TELEPHONE NO.		21E. COMMERCIAL TELEPHONE NO.	
		AREA CODE ()	